

## REMARKS

The applicant appreciates the Examiner's thorough examination of the application and requests reexamination and reconsideration of the application in view of the preceding amendments and the following remarks. The applicant also appreciates the Examiner's indication that claims 14-15, 17-20, 34-40, 42 and 45-47 are allowed and claims 3, 6, 8-9, 12-13, 23, 26, 28-29 and 32-33 are allowable.

The Examiner rejects claims 1, 2, 4-5, 7, 10-11, 21-22, 24-25, 27, 30-31 and 43-44 under 35 USC §103(a) as being unpatentable over U.S. Patent No. 5,741,260 to *Songer et al.* in view of U.S. Patent No. 5,476,465 to *Preissman*.

Claim 1 of the subject application is directed to a crimping system. A crimp tube has an aperture formed along a long axis of the crimp tube for a suture to be located within the aperture of the crimp tube. A set of crimp devices are provided for attachment to first and second portions of the suture. Claim 1 also recites a unique crimping tool. Two arms each have a proximal end and a distal end, the proximal end comprising a handle and the distal end comprising a jaw. A first crimping member is integral with the first jaw and has a first inner surface width. A second crimping member is integral with the second jaw and has a second inner surface width.

The Examiner alleges that:

Since *Songer* discloses two cables, each with a crimping tube, *Songer*'s kit has two crimping tubes. As one can be the claimed tube, the other can be one of the claimed crimp devices. The fact that the crimp tubes are not disclosed as being for attachment to 1<sup>st</sup> and 2<sup>nd</sup> portions of a suture is not persuasive because if one so desired, one could place both ends of one suture in opposite ends of one crimp tube. That would leave one other crimp tube to be one of the claimed crimp devices. As the examiner previously pointed out, to have provided more crimp tubes in the set so that multiple procedures could be performed is obvious. A set with 3 crimp

tubes would allow 1 to be the claimed crimp tube and the other two to be the crimp devices.

*Songer*'s kit does not in fact have two crimping tubes. *Songer* is directed to a cable system for a bone securance. The system of *Songer* includes surgical crimping pliers 10 which comprise a pair of operating handles 12, 14 and connected, opposing, crimping jaws 16, 18. The jaws define opposed recesses for carrying and crimping a tubular crimp member 36 which is configured to carry a plurality of multistrand cable sections. A capstan 44 is carried on one of the handles for winding cable portions carried by the crimp member.

In operation of the *Songer* system, end portions 32a, 34a of cable 42 extend within crimp 36 and along pliers handle 12 to capstan member 44. Both end portions 32a, 34a are tightened about the drums of the capstan. Then, pliers 10 are activated to crush crimp 36, and end portions 32a, 34a outside of crimp 36 may be cut and removed. See Col. 3, line 56-Col. 4, line 26 of *Songer*.

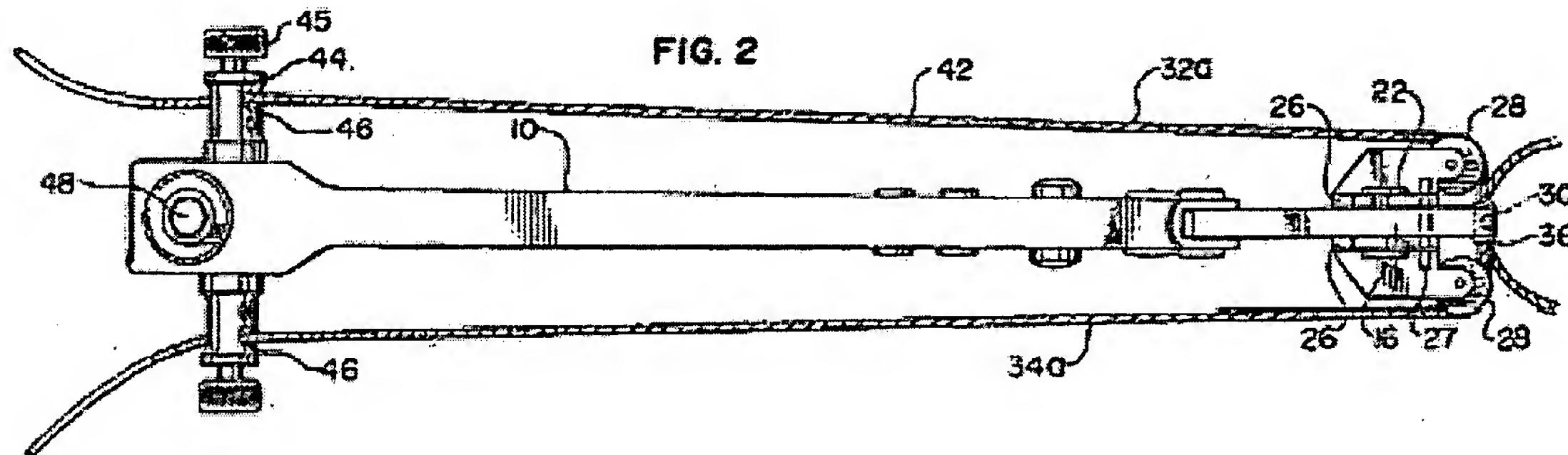
The *Songer* system includes a single cable and a single crimp tube. Figure 8 of *Songer* shows two separate systems being used to close a sternum. *Songer* states that "In Fig. 8, a closure of the sternum is seen, using a pair of cable windings, which may be simultaneously applied with a pair of pliers 10, or sequentially applied with the same set of pliers." (emphasis added) Col. 4, lines 27-30 of *Songer*. Each system of *Songer* includes one cable winding and only one crimp tube used in conjunction with the cable.

Nowhere does *Songer* disclose, teach or suggest providing multiple crimp tubes for use with a cable. And, there is no need to provide multiple crimp tubes in the *Songer* system as *Songer* only discloses using one crimp tube in conjunction with a cable. As *Songer*'s system includes only one crimp tube for use with the cable, the applicant submits that *Songer*'s kit fails to include two crimping tubes as alleged by the Examiner.

Accordingly, as *Songer* fails to disclose, teach or suggest providing multiple crimp tubes for use with a cable, and since each system of *Songer* includes only one crimp tube, it would not be obvious to provide more crimp tubes in the *Songer* system. As *Preissman* also fails to disclose the crimp devices as claimed by the applicant, independent claims 1 and 21, and their respective dependent claims, are patentable over the cited references.

Further, the applicant submits that *Songer* teaches away from providing a set of crimp devices for attachment to first and second portions of the suture to place the suture in tension as claimed by the applicant.

*Songer* discloses that end sections 32a, 34a of the cable of *Songer* extend about a respective wheel 28 and then rearwardly along the pliers' handle 12 to a capstan member 44. Capstan member 44 includes a shaft which carries a pair of rotary drums 46 on opposite sides of handle 12, with shaft 45 extending completely through handle 12. Shaft 48 also extends through the end of handle 12 to serve as a single, rotating handle for controlling the winding of drums 46. A torque wrench is used to engage shaft 48, and is rotated to cause rotation of shaft 45 and drums 46. This results in a tightening of cable ends 32a, 34a. See Col. 3, line 56 – Col. 4, line 10 and Figs. 1 and 2 of *Songer*. Figure 2 of *Songer* is reproduced below for reference purposes.

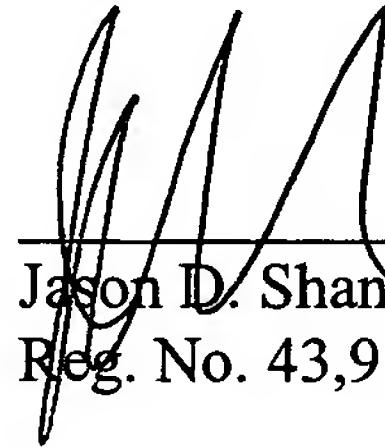


Attaching crimp devices to first and second portions of the suture of *Songer* would interfere with the operation of the *Songer* pliers system. If crimp devices are attached to the tips of end sections 32a, 34a of *Songer*, then the crimp devices will prevent end sections 32a, 34a from being threaded through drums 46. If crimp devices are attached further along end sections 32a, 34a of *Songer*, then they will limit how much the cable ends can be tightened. During the tightening of the cable ends, such crimp devices would eventually be pulled into contact with drums 46. At that point, no further tightening of the cable ends could occur due to the interference of the crimp devices.

Accordingly, it is clear that attaching crimp devices as claimed by the applicant to the cable of *Songer* would interfere with the operation of the *Songer* system. Therefore, the applicant submits that *Songer* teaches away from attaching crimp devices to the cable as claimed by the applicant. As such, the claims of the subject application are clearly patentable over *Songer* for at least this additional reason.

If for any reason these Preliminary Remarks are found to be incomplete, or if at any time it appears that a telephone conference with counsel would help advance prosecution, please telephone the undersigned or his associates, collect in Waltham, Massachusetts, at (781) 890-5678.

Respectfully submitted,



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